US ERA ARCHIVE DOCUMENT

SEPA 4-CPA TRED Facts

Environmental Protection

United States

Agency

EPA has assessed the risks associated with the use of 4-Chlorophenoxyacetic Acid (4-CPA), and completed a Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (known as a TRED) for this pesticide. As a result of the TRED, the Agency has determined that the risks posed by the used of 4-CPA fits into its own "risk cup," meaning its risks are within acceptable levels.

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to review all the tolerances (legal limits for residues in food) for registered chemicals in effect on or before the date of the enactment of the FQPA. Tolerances are considered reassessed once the safety finding has been made or a revocation occurs. EPA completed a 4-CPA Reregistration Eligibility Decision (RED) prior to FQPA of 1996 enactment; therefore, tolerances needed to be reassessed to meet the FQPA standard.

In reviewing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. However, for 4-CPA, the only potential exposure anticipated is via ingestion of food. There is no exposure expected through consumption of drinking water given the enclosed nature of the chemical's use, and there are no registered residential uses. So aggregating exposures from the food, drinking water, and residential pathways of exposure is not necessary.

The Agency has evaluated the dietary risk associated with 4-CPA and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to residues of 4-CPA. Therefore, no mitigation measures are needed and the tolerance established for residues of 4-CPA in/on the raw agricultural commodity is now considered reassessed as safe under §408(q) of the FFDCA.

Use Summary

- 4-CPA is an herbicide used specifically as a plant growth regulator to restrict root growth during seed germination of mung beans.
- 4-CPA is applied to a water bath to soak the beans. After the beans have soaked for several hours, they are washed to remove the surface residues, and are then germinated indoors for

several days. After sprouting, the hulls and roots are discarded, and the remaining portion is canned and sold for human consumption.

• Approximately 20 lbs of 4-CPA active ingredient (a.i.) is used annually.

Health Effects

• The Agency is not concerned with any carcinogenic potential of 4-CPA.

Dietary (food and drinking water) Risks

- No effects were identified for acute dietary exposure. Therefore, due to the limited use and
 use patterns of 4-CPA, the Agency concluded that chronic dietary exposure was the only
 exposure scenario to consider.
- The chronic dietary risk for the most highly exposed population subgroup, children 1 to 6 years, is negligible (less than 0.2% of the chronic Population Adjusted Dose or cPAD) and therefore, not of concern to the Agency.
- There is no exposure expected through consumption of drinking water due to its limited indoor use.

Occupational and Ecological Risks

- Occupational and ecological risk management decisions were made as part of the 1995 RED. No new data pertaining to these types of exposures has been received.
- The Agency has determined that given the limited usage of this chemical in total annual pounds used and geographic area used, there are unlikely to be risks to endangered species associated with the use of 4-CPA.

Label Amendments/Risk Mitigation

 In completing this TRED, the Agency did not identify any label amendments which should be implemented.

Tolerance Reassessment Decisions

• The existing mung bean tolerance for 4-CPA has been reassessed. It will be lowered from 2.0 ppm to 0.2 ppm. One other tolerance, for tomatoes, will be revoked because 4-CPA use on tomatoes is no longer supported or on the current label.

Next Steps

• A Notice of Availability of the 4-CPA TRED and other supporting documents, including risk assessments and the comments on the preliminary risk assessment will be published in the *Federal Register*. A copy of the TRED and all supporting documents will also be available through the Agency's electronic public docket and comment system, EPA Dockets, and in the OPP public docket for viewing. You may access EPA dockets at www.epa.gov/edocket/. The 4-CPA docket ID number is OPP-2003-0124.